



ANALYTICAL RESEARCH LABORATORIES

840 RESEARCH PARKWAY, SUITE 546

OKLAHOMA CITY, OK 73104

PHONE (405) 271-1144

FAX (405) 271-1174

Certificate Of Analysis

CLIENT: New England Compounding Center-MA

ARL #: 118438-01

LOT #: 09182009@59

DESCRIPTION: Erythromycin 0.5% Ophthalmic Ointment

DATE RECEIVED: 09/ 21/ 2009

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 10 mL syringe w/ 6 mL each

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Erythromycin Specifications = 90% - 120%	0.5	%	0.743	148.6%	HPLC	9/ 24/ 2009

Michel Ben - Laboratory Supervisor

09/ 24/ 2009

Date Reported

ARL Form QUF-078-V3 03/02/09



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Microbiology Report

CLIENT: New England Compounding Center-MA

ARL #: 118438-01

LOT #: 09182009@59

DESCRIPTION: Erythromycin 0.5% Ophthalmic Ointment

DATE RECEIVED: 09/ 21/ 2009

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 10 mL syringe w/ 6 mL each

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (* Preliminary *)	Sterile / Not Sterile	Sterile	USP 71	09/ 21/ 2009

Sterility - An Initial report will be issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - An Initial report will be issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: $EL = K/M$ where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg

Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)

Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.

Dermal Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m²/hour × 1.80 m²)/70 Kg.

09/ 24/ 2009

Tiffany Mabry - Microbiologist

Date Reported

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